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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/219,442	12/23/1998	JING-SHAN HU	PF112P2D1	4797
22195	7590	01/05/2004	EXAMINER	
HUMAN GENOME SCIENCES INC 9410 KEY WEST AVENUE ROCKVILLE, MD 20850			LANDSMAN, ROBERT S	
			ART UNIT	PAPER NUMBER

1647

DATE MAILED: 01/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Applicati n No.

09/219,442

Applicant(s)

HU ET AL.

Examin r

Robert Landsman

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 33-132, 145-304 and 367-446 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

Continuation of Disposition of Claims: Claims withdrawn from consideration are 45-52,65-72,85-92,105-112,125-132,157-164,177-184,197-204,217-224,237-244,257-264,277-284,297-304,379-386,399-406 and 419-426.

Continuation of Disposition of Claims: Claims rejected are 33-44,53-64,73-84,93-104,113-124,144-156,165-176,185-196,205-216,225-236,245-256,265-276,285-296,367-378,387-398,407-418 and 427-446.

## **DETAILED ACTION**

### ***1. Formal Matters***

- A. Claims 33-132, 145-304, and 367-446 are pending. Claims 45-52, 65-72, 85-92, 105-112, 125-132, 157-164, 177-184, 197-204, 217-224, 237-244, 257-264, 277-284, 297-304, 379-386, 399-406, and 419-426 have been withdrawn. Therefore, claims 33-44, 53-64, 73-84, 93-104, 113-124, 144-156, 165-176, 185-196, 205-216, 225-236, 245-256, 265-276, 285-296, 367-378, 387-398, 407-418 and 427-446 are the subject of this Office Action.
- B. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

### ***2. Information Disclosure Statement***

- A. The Information Disclosure Statement filed 2/8/00 has been considered and initialed by the Examiner.
- B. The Information Disclosure Statement filed 3/16/01 has been considered and initialed by the Examiner. References ER and EW have been lined through since there is no publication date cited.

### ***3. Claim Objections***

- A. All claim objections have been withdrawn in view of Applicants' amendments to recite "expressing a protein fragment of the protein encoded by the cDNA . . ."

### ***4. Double Patenting***

- A. Claims 33-44, 53-64, 73-84, 93-104, 113-124, 145-156, 165-176, 185-196, 205-216, 225-236, 245-256, 265-276, 285-296, 367-378, 387-398, 407-418 and 427-438 remain provisionally rejected as being obvious over U.S. Applications 09/257,272, 09/935,726 and 09/107,997. Applicants have stated that they will file a Terminal Disclaimer once allowable subject matter has been identified.
- B. Claims 33-132, 145-304 and 367-446 remain provisionally rejected as being obvious over claim 18 of U.S. Applications 10/060,523. This is a provisional double patenting rejection since the conflicting claims have not yet been patented. Applicants have stated that they will file a Terminal Disclaimer once allowable subject matter has been identified.

Art Unit: 1647

C. The provisional rejection of claims 33-132, 145-304 and 367-446 over claims 38 and 42-71 of U.S. Application 09/499,468 has been withdrawn in view of the cancellation of claim 38 and the amendment of claim 42 in U.S. Application 09/499,468 to recite "a method of treating a patient having an injury to or degeneration of a photoreceptor cell" and to recite "a therapeutically effective amount" of the VEGF-2 protein. Neither of these claim amendments are disclosed or suggested by the claims recited in the above captioned application.

D. Claims 62-89 and 111-150 remain provisionally rejected under the judicially created doctrine of double patenting over claim 86 of copending Application No. 10/127,551. This is a provisional double patenting rejection since the conflicting claims have not yet been patented. Applicants have stated that they will file a Terminal Disclaimer once allowable subject matter has been identified.

***5. Claim Rejections - 35 USC § 112, first paragraph - enablement***

A. All rejections under 35 USC 112, first paragraph, enablement, have been withdrawn in view of Applicants' amendment to the claims to recite "residues 108-188" and to recite a specific function. Similarly, Applicants arguments regarding "mature" have been deemed persuasive, as discussed in the Interview Summary dated 9/15/03.

***6. Claim Rejections - 35 USC § 112, first paragraph - written description***

A. Claims 33-44, 53-64, 73-84, 93-104 and 367-378 remain rejected under 35 USC 112, first paragraph, for the reasons already of record on pages 8-9 of the Office Action dated 4/17/03. Applicants argue that a crucial step in determining the meaning of a technical claim term is to determine the ordinary meaning that would be ascribed by a person skilled in the relevant art. Additionally, technical publications can be used to confirm the skilled artisan's definition of a technical claim term, as well as to show that the patentee intended to apply that definition. Applicants argue that page 11, lines 11-21 of the specification defines the terms "mature" and "proprotein" and that these terms are consistent with those used in the art. They further argue that determining the amino acid sequence would be routine and that Applicants have provided a third party publication that demonstrates VEGF-2 is processed similarly in different cell types. Finally, Applicants argue that if one of skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing, even if every nuance of the claim is not explicitly described in the specification, then the adequate written description requirement is met.

Art Unit: 1647

These arguments have been considered, but are not deemed persuasive. First, though the term “mature” and “proprotein” may very well have accepted meanings to those of ordinary skill in the art, the issue remains that Applicants have not provided adequate written description of the amino acid sequence of these forms. Therefore, the skilled artisan would not know when they were in possession of the mature form or proprotein form of the VEGF receptor. These forms may, in fact, be identifiable. However, the specification does not identify these forms by a specific amino acid sequence. Similarly, even if the ‘mature portion’ is naturally and inherently expressed by a host cell, or is similarly expressed in various cells, the issue remains that Applicants have not provided the amino acid sequence of this protein. Therefore, the Applicant has not clearly allowed the artisan to recognize that the Applicant has invented what is claimed. Applicants’ definition of these terms in the specification do not remedy this situation since, again, no detail as to the structure of the mature or proprotein forms has been provided. It is believed that all pertinent arguments have been addressed.

## **7. Conclusion**

A. No claim is allowable.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Art Unit: 1647

***Advisory information***

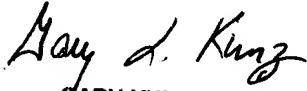
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.  
Patent Examiner  
Group 1600  
December 18, 2003

  
GARY KUNZ  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600